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**BIOSOUND**  
AN ESAOTE COMPANY

## Safety and Effectiveness Summary

The following safety and effectiveness summary has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR §807.92(a).

### 807.92(a)(1)

#### **Submitter Information**

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### 807.92(a)(2)

Trade Name: LP13 Laparoscopic Transducer

Common Name: Diagnostic Ultrasound Transducers

Classification Name(s): Transducer, Ultrasonic, Diagnostic 892.1570

### 807.92(a)(3)

#### **Predicate Device(s)**

- Aloka UST 5522 - 7.5 Transducer K925486

807.92(a)(4)

## **Device Description**

The LP13 is a diagnostic ultrasound transducer intended to be used in laparoscopic surgical procedures. The transducer is introduced into the abdomen through a trocar following the procedure described in the operator's manual. The distal tip of the device contains the transducer element and is movable. Movement of the transducer is controlled by the levers located on the handle of the device.

## **Specifications**

Intended use	Abdominal, Laparoscopic
Operating Modes	B, M, PW, CFM
Operating Frequencies	
B - Mode	7.5 - 10.0 Mhz
M - Mode	7.5 - 10.0 Mhz
PW- Mode	3.5, 4.7 - 7.0 Mhz
CFM -	3.5, 4.7 - 7.0 Mhz
Movement Range of Transducer	+/- 90°
Cable Length	3 Meters
Operating Temperature	+5 to +35 C°
Storing Temperature	-5 to +45 C°
Weight	0.3 Kg
Safety Standard	IEC 601-1 (CEI 62-5)

The materials comprising the transducer are the same as those described and accepted in K941935. The materials are listed here again for reference:

- 1) PVC from Putnum Plastics
- 2) Ultem from General Electric Plastics
- 3) FDA TRA-Bond Epoxy

## **Sterilization**

Sterilization can be accomplished in the same way as described in K941935 for the LP12 transducer, with Cidex™ solution. Cidex™ solution was cleared by the FDA under K924434. The procedure is described in the operator's manual.

807.92(a)(5)

### Intended Use(s)

The LP13 is a diagnostic ultrasound transducer for use in laparoscopic surgery. The transducer can be used to image abdominal anatomy during laparoscopic surgical procedures. In Doppler mode, the transducer can provide information about blood flow in abdominal vessels

807.92(a)(6)

### Substantial Equivalence

## Substantial Equivalence Comparison Table

Characteristic	Esaote LP13	Aloka UST5522 K925486
Intended Use	Abdominal Laparoscopic	Abdominal Laparosco pic
Technology	Linear Array	Linear Array
Operating Modes	B, PW, M, CFM	B, PW, M
Diameter	9.5 mm	10.0 mm
Moveable Transducer	Yes	No
Frequencies	7.5 - 10.0 Mhz	7.5 Mhz
Safety Standard	IEC 601-1	IEC 601-1

The table above illustrates the equivalence of the compared devices. The LP13 offers an additional mode which enhances its clinical utility. A moveable transducer allows the operator to achieve the best image by achieving an optimum imaging position; a feature not offered by the Aloka device. Based on the above comparison and in light of the minor differences noted, we believe the devices compared above are substantially equivalent